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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 522

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Certifier	<i>[Signature]</i>

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for 12 approved new animal drug applications (NADA's) from Merial Ltd. to Phoenix Scientific, Inc.

DATES: This rule is effective *[insert date of publication in the Federal Register]*.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0213.

SUPPLEMENTARY INFORMATION: Merial Ltd., 2100 Ronson Rd., Iselin, NJ 08830-3077, has informed FDA that it has transferred ownership of, and all rights and interests in, the following approved NADA's to Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506-0457:

NADA No.	Product Name
033-157	SPECTAM® (spectinomycin) Scour Halt
040-040	SPECTAM® (spectinomycin) Injection
045-416	BUTATRON™ (phenylbutazone) Injection
048-287	Oxytetracycline-50 (oxytetracycline) Injection
055-002	TEVOCIN (chloramphenicol) Injection
093-483	SPECTAM® (spectinomycin) Injectable
119-142	PVL Iron Dextran Injectable
123-815	Dexamethasone Sodium Phosphate Injection
124-241	PVL Oxytocin Injection
128-089	ZONOMETH (dexamethasone) Sterile Solution
200-147	GENTA-JECT® (gentamicin sulfate) Injection
200-153	NEO 200 (neomycin sulfate) Oral Solution

Accordingly, the agency is amending the regulations in parts 520 and 522 (21 CFR parts 520 and 522) in §§ 520.1485, 520.2122, 522.390, 522.540, 522.1044, 522.1183, 522.1662a, 522.1680, and 522.2120 to reflect the transfer of ownership. An entry for Phoenix Scientific, Inc., already exists in § 522.1720 *Phenylbutazone Injection* following the approval of a supplemental ANADA 200-126 (61 FR 54332, October 18, 1996).

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Parts 520 and 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 520 and 522 are amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.1485 [Amended]

2. Section 520.1485 *Neomycin sulfate oral solution* is amended in paragraph (b) by removing “050604”.

§ 520.2122 [Amended]

3. Section 520.2122 *Spectinomycin dihydrochloride oral solution* is amended in paragraph (b)(1) by removing “050604” and adding in its place “059130”.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

4. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.390 [Amended]

5. Section 522.390 *Chloramphenicol injection* is amended in paragraph (b) by removing “050604” and adding in its place “059130”.

§ 522.540 [Amended]

6. Section 522.540 *Dexamethasone injection* is amended in paragraphs (d)(2)(i) and (e)(2) by removing “050604” and adding in its place “059130”.

§ 522.1044 [Amended]

7. Section 522.1044 *Gentamicin sulfate injection* is amended in paragraph (b)(4) by removing “050604” and adding in its place “059130”.

§ 522.1183 [Amended]

8. Section 522.1183 *Iron hydrogenated dextran injection* is amended in paragraph (e)(1) by removing “050604” and adding in its place “059130”.

§ 522.1662a [Amended]

9. Section 522.1662a *Oxytetracycline hydrochloride injection* is amended in paragraph (i)(2) by removing “050604” and adding in its place “059130”.

§ 522.1680 [Amended]

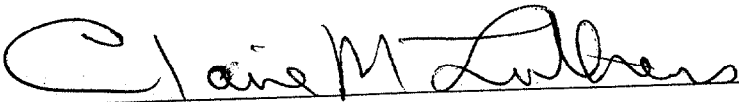
10. Section 522.1680 *Oxytocin injection* is amended in paragraph (b) by removing “050604” and adding in its place “059130”.

§ 522.2120 [Amended]

11. Section 522.2120 *Spectinomycin dihydrochloride injection* is amended in paragraph (b) by removing "050604" and adding in its place "059130".

Dated: July 18, 2000

July 18, 2000



Claire M. Lathers
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Office of New Animal Drug Evaluation
Center for Veterinary Medicine

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